

**UNITED STATES DISTRICT COURT  
DISTRICT OF MASSACHUSETTS**

**SERONO, INC.**

**Plaintiff**

**v.**

**FERRING PHARMACEUTICALS, INC.**

**Defendant**

Civil Action No. 02-11832MLW

**PLAINTIFF SERONO, INC.'s  
REPLY BRIEF ON CLAIM CONSTRUCTION**

Fred A. Kelly, Jr. (BBO # 544046)

**NIXON PEABODY LLP**

101 Federal Street

Boston, MA 02110-1832

Ph: (617) 345-1000

Fax: (617) 345-1300

Timothy J. Waters

Craig P. Seebald

Joel R. Grosberg

Stefan M. Meisner

**MCDERMOTT, WILL & EMERY**

600 13th Street, N.W.

Washington, DC 20005-3096

Ph: (202) 756-8000

Fax: (202) 756-8087

Daniel A. Boehnen

Grantland G. Drutchas

Joshua R. Rich

Nicole A. Fiorella

**MCDONNELL BOEHNEN HULBERT & BERGHOFF**

300 S. Wacker Drive

Chicago, Illinois 60606

Ph: (312) 913-0001

Fax: (312) 913-0002

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only conflict with the intrinsic evidence and the plain meaning of the claim terms as would be understood by a person of skill in the art but also violate the governing legal rules.

As to terms (iv) and (v) above, Serono's and Ferring's proposed constructions are similar, but still retain some inconsistency. Serono's proposed constructions more closely track the intrinsic evidence, while Ferring's proposals raise further issues. As a result, this Court should adopt Serono's proposed construction of all five terms.

**A. "Absence of Exogenous LH" and "Without the Presence of Exogenous LH"**

The parties agree that these two phrases mean essentially the same thing as one another, but the parties disagree as to what that thing is. Serono contends the phrases should be construed in relation to the limit of what was possible to do at the time in question, *i.e.*, such that "absence of exogenous LH" means that the bioassay technology at the time in question was unable to detect or measure the presence of any LH bioactivity in the exogenous FSH. By contrast, Ferring contends that the phrases require an absolute state of being, such that there is absolutely no LH present in the exogenous FSH.

Significantly, the parties also agree that all claim terms must be construed as understood by one of ordinary skill in the art at the time the patent application was filed, *i.e.*, as of 1984 in this case. *See* Serono Br., p. 11 (citing *Schering Corp. v. Amgen, Inc.*, 222 F.3d 1347, 1353 (Fed. Cir. 2000)); Ferring Br., p. 5 (quoting *Markman v. Westview Instr., Inc.*, 52 F.3d 967, 986 (Fed. Cir. 1995), *aff'd*, 517 U.S. 370 (1996) ("the focus is on the objective test of what one of ordinary skill in the art at the time of the invention would have understood the term to mean")). Thus, this Court's key challenge in construing the pertinent phrases is determining how one of ordinary skill in the relevant art as of 1984 would know whether a composition had "FSH . . . in the absence of exogenous LH" or "FSH alone . . . without the presence of exogenous LH."

Serono's construction is consistent with the understanding of a skilled person in 1984. Not only is Ferring's proposed definition inconsistent with the understanding of persons skilled in the art as of 1984, as will be shown below, but also Ferring's requirement for "absoluteness" requires an impossibility, namely a standard that would have been impossible to achieve for any urinary-derived FSH product in 1984. Even today, it would be impossible to prove that a urinary-derived gonadotropin is absolutely free of LH because any and all pertinent tests have an inherent lower limit of detection or measurability. It is impossible to determine whether LH is or is not present below the lower limit of detection, *i.e.*, where the LH is not measurable.

Ferring does not and cannot dispute that those of skill in the art in 1984 would determine whether LH was present by testing for LH bioactivity.<sup>1</sup> Furthermore, Ferring does not and cannot deny that such tests are not absolute. In fact, as Ferring surely recognizes, very few things (if anything) in biochemical pharmaceuticals are absolute. Those of skill in the art in 1984 concluded that FSH was pure by testing whether the sample had any detectable LH bioactivity, for example, by using the Van Damme bioassay. Serono Br., Exs. 6, 12, 13, 14, 15; *see also* Serono Br., Ex. 16.

The Official U.S. Monograph for human menopausal gonadotropin, Serono Br., Ex. 18, published by the U.S. Pharmacopeia standards body, is the authoritative source for defining

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<sup>1</sup> In its brief, Ferring objected to a minor clarifying amendment made in Serono's claim chart. Ferring complained that the change was made a few days after Serono filed its original claim chart. Ferring's position is remarkable for at least several reasons. First, Ferring belatedly filed its own claim chart after the Court's deadline, but Serono did not complain. Second, the change merely clarified, but did not change, Serono's position. That is, the change only narrowed Serono's definition. Specifically, the change was to clarify that the pertinent 1984 standards were biological assays. *Compare* Ferring Br., Ex. H, p.1 to Ex. 19, p. 1. Third, Ferring is not prejudiced in any way by the correction, and it does not claim to be. The clarification does not affect either party's position.

In any event, to the extent that Ferring's objection to Serono's amendment justifies consuming the Court's time, Serono hereby requests the Court's permission to rely upon the corrected claim construction chart as previously served on Ferring.

pharmaceutical compositions. *See Texas Digital Sys., Inc. v. Telegenix, Inc.*, 308 F.3d 1193, 1202-03 (Fed. Cir. 2002) (“Dictionaries, encyclopedias and treatises, publicly available at the time the patent is issued, are objective resources that serve as reliable sources of information on the established meaning that would have been attributed to the terms of the claims by those of skill in the art.”); *CCS Fitness, Inc. v. Brunswick Corp.*, 288 F.3d 1359, 1366 (Fed. Cir. 2002) (quoting *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1584 n. 6 (Fed. Cir. 1996)). The Official U.S. Monograph for human menopausal gonadotropins recites the LH standard assay to be used to detect or measure LH biological activity. It is the same bioassay standard proposed by Serono. Ferring’s proposal is inconsistent with – contradicted by – the Official U.S. Monograph of the U.S. Pharmacopeia. Serono Br., Ex. 18. A person of ordinary skill in the art at the pertinent time, by reference to the Official U.S. Monograph, would have defined a composition as being “FSH . . . in the absence of exogenous LH” or “FSH alone . . . without the presence of exogenous LH” if it had an undetectable level of LH bioactivity according to the then-current U.S. Pharmacopeia-recognized assays. *Id.* Thus, one of skill in the art in 1984 would not have adopted Ferring’s absolute definition because there is no way of establishing an absolute absence of LH in such a product.

Another key tenet of claim construction, not rebutted by Ferring’s brief, is that a claim should be construed so as to include the inventor’s preferred embodiment of the claimed invention. *Johns Hopkins University v. Cellpro, Inc.*, 152 F.3d 1342, 1355 (Fed. Cir. 1998); *Gentry Gallery, Inc. v. Berkline Corp.*, 134 F.3d 1473, 1477 (Fed. Cir. 1998); *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1583 (Fed. Cir. 1996) (an interpretation that excludes a preferred embodiment is “rarely, if ever, correct and would require highly persuasive evidentiary support”). As established in Serono’s opening brief, the inventors’ preferred – indeed, the only –

embodiment in the specification for “FSH . . . in the absence of exogenous LH” or “FSH alone . . . without the presence of exogenous LH” was Serono’s FSH product known by the trade name Metrodin®. Serono Br., p. 13-17. This was the substance discussed in the prosecution of the ‘077 and ‘402 patents. *See* Serono Br., Ex. 1, col. 2, lines 65-66, col. 3, lines 32-35; Exs. 3, 8. Ferring’s proposed definition would improperly exclude the embodiment disclosed in the specification. Contemporaneous publications also confirm that persons of skill in the art as of 1984 understood the pertinent terms as referring to the “pure” FSH used by the inventors – namely Urofollitropin/Metrodin® – as meaning FSH that had no detectable LH bioactivity. *See, e.g.,* Serono Br., Ex. 1, col. 3, lines 19-21; Exs. 6, 7, 15.

Serono’s proposed construction is also consistent with the context of the prosecution history of the ‘077 and ‘402 patents, whereas Ferring’s proposal is not. Unmistakably, the intrinsic evidence demonstrates that these phrases are to be construed as meaning an undetectable, or unmeasurable, level of LH bioactivity using the referenced bioassay standards:

The fact that pure FSH can stimulate dynamic follicular growth in the absence of measurable LH is completely contrary to the accepted dogma and completely unexpected.

Ex. 20, p. 5; *see also* Serono Br., p. 14-16. Ferring simply ignores such explicit language. Instead, Ferring’s brief cites two references to the prosecution history that were intended to distinguish prior art using the language of the claims. *See* Ferring Br., p. 15 (quoting Ferring Br., Exs. C, G). Those passages do not explain or define the pertinent phrases. *Id.*

Ferring also ignores the fact that each and every reference it cites discussed the effect of the claimed treatment in female patients. Ferring Br., Ex. F, p. 3; Ex. G, p. 2-3. Such discussions necessarily and inherently involve biological activity *in vivo*. In other words, Ferring’s own citations to the prosecution history establish that the invention was understood in

the context of a finding that the FSH product having no LH bioactivity worked for achieving fertility in female patients. Ferring Br., p. 10. The intrinsic evidence of the preferred embodiment of the '077 and '402 patents therefore shows that this Court should adopt Serono's construction of "absence of exogenous LH" and "without the presence of exogenous LH."

Above and beyond the accepted rules of claim construction, even the policies underlying claim construction suggest that Ferring's proposed construction is wrong. It is undisputed (and indisputable) that Urofollitropin/Metrodin<sup>®</sup> products were (and are) derived from urine of postmenopausal women, and that such urine includes both FSH and LH. Serono Br., Exs. 12, 13. For Urofollitropin, LH was removed to a point at which it had no detectable bioactivity by the methods employed. *See* Serono Br., Exs. 6, 7, 12, 13, 15. Nevertheless, since Urofollitropin is a natural product, it would have been understood to have necessarily contained some LH. As a result, under Ferring's absolute definition of the "absence of exogenous LH" and "without the presence of exogenous LH," the preferred Urofollitropin/Metrodin<sup>®</sup> embodiment of the invention would be excluded from the scope of the claims. In contrast, the preferred Urofollitropin/Metrodin<sup>®</sup> embodiment falls within the scope of Serono's proposed construction, as testing demonstrated no detectable LH bioactivity. *Id.*

Finally, Ferring's proposed construction must be wrong because it prevents an accused infringer from knowing whether it infringes and may be subject to suit. Despite Ferring's purported desire to establish an "absolute" meaning of the terminology, Ferring's approach, including ignoring the lower limit of detection or measurement, actually robs the patent claim of any practical meaning. Ferring Br., p. 13, 16. That is, under Ferring's proposed construction, either party could assert that a method did or did not infringe the claims of the '077 and '402 patents, but neither party would ever be able to prove its assertion conclusively. Under Ferring's

scenario, the Court would have to decide whether there is LH present, but would be unable to rely on the tests used to detect its presence, such as the Van Damme method referenced in articles as of 1984. Serono Br., Exs. 6, 7, 16. That situation would be something like trying to decide whether a tree falling in the forest makes any noise if nobody is around to hear it.

Even more ambiguously, under Ferring's proposal, the meaning of "absence of exogenous LH" and "without the presence of exogenous LH" may change based upon later-developed technology. Future technology might show that LH bioactivity was caused by some substance other than LH, or future technology might detect an inactive form of LH not previously recognized. In the former case, the claims of the '077 and '402 patents would grow broader over time; in the latter case, the claims would grow narrower. Claim interpretation is not supposed to be affected by the passage of time and later developed technology because this would deny the certainty and "uniformity in treatment of a given patent" that the Supreme Court sought through assigning claim construction to the judge. *Markman v. Westview Instr., Inc.*, 517 U.S. 370, 390 (1996).<sup>2</sup> Rather, the impact of later developed technology on patent infringement is dealt with through the doctrine of equivalents. *See, e.g., Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 344 F.3d 1359 (Fed. Cir. 2003). Indeed, Ferring's proposed construction

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<sup>2</sup> The *Markman* court noted the benefit of a consistent definition of claim terms and the harm of changing definitions:

As we noted in *General Elec. Co. v. Wabash Appliance Corp.*, 304 U.S. 364, 369 (1938), "[t]he limits of a patent must be known for the protection of the patentee, the encouragement of the inventive genius of others and the assurance that the subject of the patent will be dedicated ultimately to the public." Otherwise, a "zone of uncertainty which enterprise and experimentation may enter only at the risk of infringement claims would discourage invention only a little less than unequivocal foreclosure of the field," *United Carbon Co. v. Binney & Smith Co.*, 317 U. S. 228, 236 (1942), and "[t]he public [would] be deprived of rights supposed to belong to it, without being clearly told what it is that limits these rights." *Merrill v. Yeomans*, 94 U. S. 568, 573 (1877).

*Id.* at 390.

would create the very evil feared by the Supreme Court for over six decades, a “zone of uncertainty” in which patentee and accused infringer would be unsure of whether there was infringement or not. *Markman*, 517 U.S. at 390 (quoting *United Carbon Co. v. Binney & Smith Co.*, 317 U. S. 228, 236 (1942)). Thus, the policies underlying claim construction suggest that Ferring’s arguments should be rejected.

Because the governing law, relevant evidence, and underlying policies all suggest that Ferring’s construction of the claim terms “absence of exogenous LH” and “without the presence of exogenous LH” is incorrect, this Court should reject it. Similarly, because the governing law, relevant evidence, and underlying policies suggest that Serono’s claim construction is correct, this Court should adopt it.

**B. “A Method of Suppressing Estrogen Variability”**

The preamble of claim 13 of the ‘077 patent notes that the invention is “[a] method of suppressing estrogen variability.” Such preamble language is generally not considered to be a limitation of the claim. *Bristol-Myers Squibb Co. v. Ben Venue Labs*, 246 Fed. 3d 1368, 1373-75 (Fed. Cir. 2001). If the preamble is treated as a limitation on the claim, however, it is subject to all the normal rules of claim construction, including the prohibition against importing additional limitations into the claim.

Serono has proposed a simple and straightforward construction for the preamble of claim 13 of the ‘077 patent, namely, that the preamble means a method of mitigating the individual variation in females of estrogen levels. *See* Ex. 19, p. 3. In contrast, Ferring argues that the phrase means “a method of suppressing estrogen variability in response to gonadotropin treatment and not for any other purpose or effect.” Ferring Br., p. 19 (emphasis added).

Comparison of Ferring’s proposal to the actual claim language shows the fallacy of Ferring’s proposal. Ferring has not actually provided any interpretation at all. Ferring merely

repeats the verbatim language in the claim, and then adds an additional limitation onto the end of the phrase. Ferring's attempt to insert an additional limitation is unsupportable both legally and factually. It violates a basic canon of claim interpretation and does not reflect the way that the GnRH antagonist functions. As result, Ferring's attempt to insert an additional limitation must be rejected. Without the new limitation, Ferring's proposed construction is completely circular and unhelpful. Thus, this Court should adopt Serono's construction of the claim 13 preamble and reject Ferring's proposal.

The parties seem to agree that the preamble of claim 13 recites a decrease in variability of estrogen levels in women in the context of gonadotropin treatment, but, according to Ferring, the purpose of decreasing estrogen variability must be the only purpose or effect that occurs during the treatment. *Compare* Ferring Br., p. 19-20 to Ex. 19, p. 3. The latter aspect of Ferring's position is fatally defective. The plain language of the claim is completely clear in stating that suppression of estrogen variability is a purpose of the claimed invention, but nothing in the claim language or the intrinsic evidence in any possible way supports that this effect is the sole and exclusive purpose.

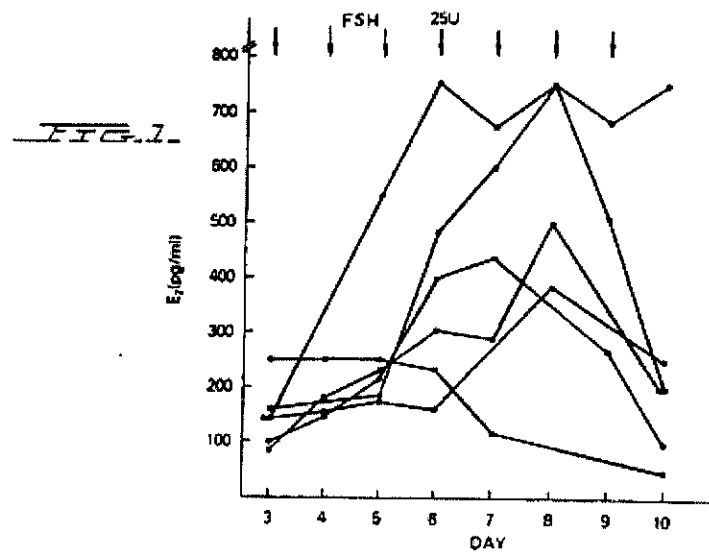
To the contrary, the preamble itself makes clear that the invention is part of a method of gonadotropin treatment. The complex processes within the human body inherently cause other effects (*i.e.*, actions and reactions) to occur during and as a result of the gonadotropin treatment. Serono Br., Ex. 2, col. 6, lines 28-34. For this reason alone, it is improper to import the unexpressed limitation of "not for any other purpose or effect" into the claim. As one of ordinary skill in the art at the time knew, a gonadotropin releasing hormone (or GnRH) antagonist does not affect estrogen levels directly. Instead, a GnRH antagonist is part of a

complex biochemical feedback mechanism within the ovulation-related hormone cycle of the female body.

As discussed below, as well as during the prosecution of the '077 patent and Ferring's opening brief, GnRH antagonists bind to GnRH receptors on cells of the pituitary gland, and do so without evoking gonadotropin secretion. *See* Ferring Br., p. 20-21, Ex. J. By binding to a GnRH receptor in this manner, a GnRH antagonist prevents the pituitary from secreting endogenous FSH and LH in response to the endogenous GnRH molecule, as the pituitary would otherwise do. *See* Serono Br., Ex. 2, col. 2, lines 22-26.

As taught and claimed by the patents, any endogenous FSH and LH would stimulate the development of the ovarian follicles, which would in turn secrete estrogen as they matured. However, as taught and claimed by the '077 patent, the clinician wants to control the rate of stimulation of the follicles and, in turn, the secretion of estrogen, and the clinician does that by controlling the administration of exogenous FSH. According to the patent, the clinician does not want the endogenous gonadotropins to influence the follicles. Thus, administration of a GnRH antagonist interrupts the endogenous cycle and reduces the variability of the estrogen level.

This was all taught in the patent according to the understanding in the art at the time. As shown in Figure 1 of the '077 patent (reproduced below), estrogen levels (shown as  $E_2$ ) in subjects undergoing gonadotropin treatment without GnRH antagonists were variable and variable in unpredictable ways.



The inventor of the subject matter claimed in the '077 patent discovered that subjects undergoing gonadotropin treatment including GnRH antagonists had far less variability in their estrogen levels. Serono Br., Ex. 2, col. 4, lines 53-58; Ex. 19, p. 3. The distinction was important not only because estrogen level is an indicator of the maturation of follicles, but also because it influences the maturation of the follicles. Thus, through the suppression of estrogen variability, a clinician could administer exogenous FSH alone or exogenous FSH and LH in combination without worrying as much about the unpredictability caused by a subject's estrogen-influenced production of endogenous FSH and LH and possible premature LH surges. Ex. 19, p. 3.

Even if this inherent science did not exist or was not true, a most basic claim construction canon is that "one may not read a limitation into a claim from the written description." *RF Del., Inc. v. Pacific Keystone Techs., Inc.*, 326 F.3d 1255, 1264 (Fed. Cir. 2003) (citing *Renishaw PLC v. Marposs Societa' per Azioni*, 158 F.3d 1243, 1248 (Fed. Cir. 1998)). This canon of claim construction would also mandate rejection of Ferring's proposal. The plain wording of the claim precludes importing the additional limitation proposed by Ferring.

Ferring tries to justify adding a limitation by arguing that the specification describes only one embodiment, and the claims should be limited to the method of that embodiment. Ferring Br., p. 19. That is a common tactic used by accused infringers; it is also just as commonly rejected by the Federal Circuit. *See, e.g., SunRace Roots Enterprise Co., Ltd. v. SRAM Corp.*, 336 F.3d 1298, 1305 (Fed. Cir. 2003) (identifying only the situation in which the patent describes the preferred embodiment as the invention itself as being one in which it would be proper to limit claim scope to preferred embodiment); *RF Del.*, 326 F.3d at 1264 (“An independent claim usually covers a scope broader than the preferred embodiment”); *Rexnord Corp. v. Laitram Corp.*, 274 F.3d 1336, 1344 (Fed. Cir. 2001) (“An applicant is not required to describe in the specification every conceivable and possible future embodiment of his invention.”). It would be legally erroneous to adopt Ferring’s proposed addition of a limitation to the preamble.

Furthermore, contrary to Ferring’s assertions, the preamble language “suppressing estrogen variability” cannot be treated as a limitation on the claims in any event. Phrases in a preamble may, in certain circumstances, serve as limitations to a claim where they recite essential structure or steps, or if they are “necessary to breathe life into a claim.” *Schumer v. Laboratory Computer Sys., Inc.*, 308 F.3d 1304, 1310 (Fed. Cir. 2002). Where, however, the preamble language is merely expressing one possible purpose, that language does not serve as a limitation on the claims. *Id.*; *see also Altiris Inc. v. Symantec Corp.*, 318 F.3d 1363, 1371 (Fed. Cir. 2003); *Catalina Mktg. Int’l v. Coolsavings.com, Inc.*, 289 F.3d 801, 808 (Fed. Cir. 2002). The specifications of the patents-in-suit clearly teach gonadotropin treatment methods that do not specifically require suppressing estrogen variability. Indeed, the other independent claims in the ‘077 patent, claims 1 and 8, do not even discuss suppressing estrogen variability.

At the outset, Ferring proposes that the Court construe the phrase as meaning “administration of conventional combinations of FSH and LH.” *See* Ferring Br., p. 17. Then Ferring goes on to say its definition really means the administration of gonadotropins with “FSH/LH ratios which approximate 1:1, with no other active ingredients.” *See* Ferring Br. at p. 18. Ferring’s strained construction is wrong on its face for multiple reasons.

Apparently unsatisfied with adding a single limitation of “conventional combinations,” Ferring goes on to say that it really means “FSH/LH ratios which approximate 1:1, with no other active ingredients.” This approach urges this Court to adopt an erroneous and illegal definition by importing two separate and distinct limitations into the claims, *i.e.*, (i) ratios that approximate 1:1, and (ii) with no other active ingredients. *SunRace Roots*, 336 F.3d at 1305. As to the 1:1 ratio, Ferring’s proposed construction also violates the doctrine of claim differentiation, as it would make the scope of claim 14 identical to the scope of claim 15. As to “no other active ingredients,” Ferring’s proposed construction also violates the requirement for intrinsic evidence because a careful reading of the specification and prosecution history shows that such limitation does not appear anywhere.

The prosecution history makes it abundantly clear that claim 14 of the ‘077 patent cannot be limited to Ferring’s “conventional FSH/LH combinations” that are really supposed to mean “FSH/LH ratios which approximate 1:1, with no other active ingredients.” *See* Ferring Br., p. 18. During prosecution before the Patent Office, the Examiner rejected an initial claim and proposed such a 1:1 ratio, stating that the disclosure was:

enabling only for claims limited in accordance with the specification directed to FSH alone or FSH and LH in combination in an approximately 1:1 I.U. ratio. . . there is insufficient guidance given to enable others skilled in the art to practice the invention with other gonadotropins or to use other LH:FSH ratios with a reasonable expectation of success.”

Ex. 21, p.2. In response, Serono filed an Amendment Under Rule 115 dated November 10, 1988, in which it argued that “there is clearly sufficient guidance given to enable others skilled in the art to practice the invention with other gonadotropins or to use other FSH:LH ratios with a reasonable expectation of success.” Serono Br., Ex. 9, p. 2. Further, Serono argued that

While the combination specifically illustrated used approximately equal amounts, the clear teaching to one skilled in the art is that whatever gonadotropin therapy is employed, the conjoint use of the antagonist results in advantageous results. Thus one skilled in the art could use any gonadotropin therapy together with the antagonist and, based on the teachings of the application, have a reasonable expectation of success.”

*Id.*, p. 3 (emphasis added). The Examiner was persuaded by this argument, withdrew his objection to claim 14, and allowed the claim to issue with the current language, and without being limited to a 1:1 FSH:LH ratio.

Instead, the 1:1 FSH:LH ratio was included into the further dependent claim 15. This intrinsic evidence shows that Ferring’s proposed reading of claim 14 is incorrect and would violate the doctrine of claim differentiation. Under that doctrine, the limitations from one claim should not be read so as to duplicate another claim because separate claims are presumed to have different scope. *Smith & Nephew, Inc. v. Ethicon, Inc.*, 276 F.3d 1304, 1310 (Fed. Cir. 2001).

Here, claim 15 reads:

15. The method of claim 14 wherein the preparation is (b) [FSH and LH in combination] and contains approximately equal I.U. amounts of FSH and LH.

Ex. 1, col. 6, lines 39-41.

Under Federal Circuit precedent it would be clearly erroneous to read the mathematical ratio from claim 15 into claim 14:

Ordinarily a claim element that is claimed in general descriptive words, when a numerical range appears in the specification and in other claims, is not limited to the numbers in the specification or the other claims. *See Specialty Composites v. Cabot Corp.*, 845 F.2d 981, 987 (Fed. Cir. 1988) (“[P]articular embodiments

appearing in the specification will not generally be read into the claims. . . . What is patented is not restricted to the examples, but is defined by the words in the claims.”). It is usually incorrect to read numerical precision into a claim from which it is absent, particularly when other claims contain the numerical limitation. In *D.M.I., Inc. v. Deere & Co.*, 755 F.2d 1570, 1574 (Fed. Cir. 1985), the court stated:

Where, as here, the limitation sought to be “read into” a claim already appears in another claim, the rule is far more than “general.” It is fixed. It is long and well established. It enjoys an immutable and universally applicable status comparatively rare among rules of law. Without it, the entire statutory and regulatory structure governing the drafting, submission, examination, allowance, and enforceability of claims would crumble.

*Modine Mfg. Co. v. U.S. Int’l Trade Com’n*, 75 F.3d 1545, 1551 (Fed. Cir. 1996).

The intrinsic evidence establishes that the “FSH and LH in combination” of claim 14 should not be limited to FSH/LH ratios which approximate 1:1, with no other active ingredients, as Ferring asserts. The rule of claim differentiation also establishes that Ferring’s proposed construction is incorrect. Thus, the Court should adopt Serono’s construction of “FSH and LH in combination” and not limit the combination to a specific ratio.

#### **D. “Cojointly”**

Claims 1 and 13 of the ‘077 patent require that the claimed method include administering a gonadotropin releasing hormone antagonist (discussed below) “cojointly” with FSH alone or a gonadotropin treatment. Serono Br., Ex. 2, col. 5, lines 25-35, col. 6, lines 28-34. There may be no dispute between the parties’ proposed definition of this term, but some clarification is required.

Serono’s proposed construction of the term “cojointly” is that it requires the administration of GnRH antagonist and the administration of gonadotropin to be relatively closely timed to each other. Serono’s proposal allows the GnRH antagonist to be administered prior to the FSH or vice versa. Although the claim refers to GnRH antagonist cojointly with FSH, it does not matter which compound goes first according to Serono’s definition.

By contrast, Ferring's brief consistently says that the claim requires FSH to be administered "together" with the GnRH antagonist, consistently referencing FSH first. That language is not in the claims or the specification. Assuming Ferring agrees that the order (or sequence) of administration does not matter, there appears to be little distinction between this aspect of the two definitions. However, Serono's proposal is more accurate and tracks the language of the claims and the specification.

In addition, Ferring's proposed interpretation requires that the two compounds must be administered the same day, which should more accurately be understood as within twenty-four hours of each other. Simply stated, there is no basis in the '077 patent or its prosecution history for suggesting that the GnRH antagonist must be administered within twenty-four hours of administering the FSH, or that "cojointly" means only the two compounds must be administered on the same day. The claims require only that a GnRH antagonist be administered at least once cojointly with FSH or a gonadotropin treatment. Serono Br., Ex. 2, col. 5, lines 25-35, col. 6, lines 28-34. To this end, the claimed method contains the word "comprising," which as a matter of law is an open-ended term such that the claims can include additional, unrecited steps. *See Georgia-Pacific Corp. v. United States Gypsum Co.*, 195 F.3d 1322 (Fed. Cir. 1999). Thus, by definition, the claimed methods can include other steps such as the administration of either compound, or some other compound, on days during which the other compound is not administered.

Similarly, there is simply no basis, either from the '077 patent or a dictionary, for suggesting that "cojoint" must mean on the same day. Nonetheless, Serono does not believe that requiring the administration of the GnRH antagonist within twenty-four hours of an administration of gonadotropin treatment, or vice versa, to be an unreasonable understanding of

“cojoint” administration and would agree to accept that as the standard of infringement. Thus, adopting in part Ferring’s proposed definition, the correct reading of this limitation is that “cojointly” comprises at least one administration of a GnRH antagonist within twenty-four hours of at least one administration of a claimed gonadotropin compound.

**E. “Gonadotropin Releasing Hormone Antagonist”**

Although Ferring contends that the parties dispute the meaning of the term “gonadotropin releasing hormone antagonist,” there appears to be no real disagreement. Ferring expresses concern that Serono’s definition of the term in terms of binding the GnRH receptor is too broad and could include GnRH agonists. Ferring Br., p. 20-21. Ferring’s concern is baseless because Serono’s definition requires not only that a gonadotropin releasing hormone antagonist bind the GnRH receptor, but also that it does so “without evoking secretion.” GnRH antagonist must do both things, and this is fully consistent with Ferring’s own definition. Ex. 19, p. 2. As Ferring notes, whether a substance evokes secretion of gonadotropins by the pituitary is a meaningful distinction between a GnRH agonist and a GnRH antagonist. Ferring Br., p. 20. Ferring appears simply to have overlooked the part of Serono’s proposed construction of “gonadotropin releasing hormone antagonist” that prohibits evoking secretion of the gonadotropins. Indeed Ferring position is completely consistent with Serono’s own position:

Ferring’s proposed definition of this claim term is based on the definition provided by the patentee during the prosecution of the patent. Specifically, in response to the First Office Action, the patentee, acting as his own lexicographer, stated that a “gonadotropin releasing hormone antagonist is a GnRH analog that binds the GnRH receptor without evoking secretion. Numerous known antagonists are described in the specification on page 7.”

Ferring Br., p. 20-21; *compare* Ex. 19, p. 2 (Serono defines the term as “A GnRH analog that binds the GnRH receptor without evoking secretion.”).

Oddly, although Ferring admits that the patent applicant expressly defined the term, Ferring proposes using different phrasing for its construction. Instead, Serono proposes to use the same language that the patent applicant used during patent prosecution. Clearly using the same terminology used during patent prosecution is the better approach because it more closely tracks the intrinsic evidence.

In practice, the distinction appears not to create a difference in meaning. Neither Serono nor Ferring is suggesting that Bravelle® is a GnRH antagonist, or that a GnRH agonist would fall within the definition of a GnRH antagonist. The claims themselves indicate that the GnRH antagonist be administered conjointly with FSH (like Bravelle®); the applicant was very clear in the prosecution of the '077 patent that the claims would not include a GnRH agonist. *See* Serono Br., Ex. 2, col. 5, lines 25-35; Ex. 8. Accordingly, it appears that there is no dispute between the parties under Serono's suggested construction of "gonadotropin releasing hormone antagonist."

### **III. CONCLUSION**

Serono's proposed construction of the disputed claim terms is supported by Federal Circuit precedent, intrinsic evidence, and underlying policies. Ferring's arguments are not. As a result, this Court should adopt Serono's proposed construction of the disputed claim terms:

(i) "absence of exogenous LH" and "without the presence of exogenous LH"; (ii) "method of suppressing estrogen variability"; and (iii) "FSH and LH in combination." To the extent there is

a difference in the parties' proposed definitions of terms (iv) "cojointly" and (v) "gonadotropin releasing hormone antagonist," Serono's definitions are more accurate and correct.

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Respectfully submitted,



Fred A. Kelly, Jr. (BBO # 544046)

**NIXON PEABODY LLP**

101 Federal Street

Boston, MA 02110-1832

Ph: (617) 345-1000

Fax: (617) 345-1300

Timothy J. Waters

Craig P. Seebald

Joel R. Grosberg

Stefan M. Meisner

**MCDERMOTT, WILL & EMERY**

600 13th Street, N.W.

Washington, DC 20005-3096

Ph: (202) 756-8000

Fax: (202) 756-8087

Daniel A. Boehnen

Grantland G. Drutchas

Joshua R. Rich

Nicole A. Fiorella

**MCDONNELL BOEHNEN HULBERT & BERGHOFF**

300 S. Wacker Drive

Chicago, Illinois 60606

Ph: (312) 913-0001

Fax: (312) 913-0002

CERTIFICATE OF SERVICE

I hereby certify that I caused a true copy of the above document to be served upon the attorney of record for each other party by u.s. mail and facsimile on January 14, 2004.

